IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	:	Examiner: **R. D. Rines**
Rincavage	:	
	:	Group Art Unit: **3626**
Serial No.: **10/086,253**	:	
	:	Date: **March 14, 2008**
Filed: **March 01, 2002**	:	
	:	

For: **SYSTEM AND METHOD FOR PREVENTING FRAUD AND MISTAKE IN THE ISSUANCE, FILING AND PAYMENT OF MEDICAL PRESCRIPTIONS**

Mail Stop –Appeal Brief
Commissioner of Patents and Trademarks

APPEAL BRIEF OF APPLICANT

Sir:

Having previously filed a Notice Of Appeal, the Applicant herein timely files this Appeal Brief in accordance with 37 C.F.R. 41 et seq.

I. REAL PARTY IN INTEREST [37 CFR §41.37(c)(1)]

The subject application is not assigned. As such, the Real Parties in Interest are the Applicants Barbara A. Rincavage and Cynthia E. Rincavage.

II. RELATED APPEALS AND INTERFERENCES [37 CFR §41.37(c)(2)]

No other related application is currently subject to an Appeal or Interference.

III. STATUS OF CLAIMS [37 CFR §41.37(c)(3)]

Claims 1 – 6 and 8 - 20 are pending in this application.

Claims 1 – 6 and 8 - 20 stand as finally rejected by the Examiner.

The claims on Appeal are Claims 1 – 6 and 8 - 20.

IV. STATUS OF THE AMENDMENTS [37 CFR §41.37(c)(4)]

An Amendment was filed by the Applicant on October 18, 2007. No other amendments were filed.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER [37 CFR §41.37(c)(5)]

The rejected claims contain two independent claims, which are Claim 1 and Claim 12. Claims 2-6 and 8-11 depend from Claim 1. Claims 13-20 depend from Claim 12

Claim 1

Pharmacists often use discretion when filling prescriptions. However, such discretion can lead to mistakes and to fraud. Claim 1 sets forth a methodology of analyzing changes made to a prescription by a pharmacist. ***(See preamble of Claim 1)*** To achieve this method, a database ***(14, Fig. 1)*** is provided. In a physician's office, a physician examines a patient and writes a prescription for that patient. ***(See method steps 42 and 44 in Fig. 3)*** The prescription is initially unfilled. Unfilled prescription data that corresponds to the prescription is entered into the database. ***(See method step 52 in Fig. 3)*** The unfilled prescription data contains information regarding a recommended pharmaceutical type and a recommended quantity recommended by the physician in the prescription. ***(well known definition)***

The patient travels to a pharmacy to have the prescription filled ***(well known)***. At the pharmacy, the unfilled prescription data is retrieved from the database. ***(See method step 62, Fig. 4)*** Using the retrieved data, the prescription is filled. ***(See method step 68, Fig. 4)*** The filled prescription contains a presented pharmaceutical type in a presented quantity. ***(well known)*** Due

to the discretion of the pharmacist, the actual pharmaceutical presented and its quantity may not correspond with the unfilled prescription data. The discrepancy may be justified or unjustified and can be caused by mistake, fraud or simple pharmacist choice. ***(Problem being addressed by invention)***

Data corresponding to how the prescription is actually filled is entered into the database by the pharmacist. ***(See method step 70, Fig. 4) (See specification, page 15, 2nd paragraph)*** The filled prescription data includes information regarding the actual presented pharmaceutical type and its quantity. ***(See specification, page 15, 2nd paragraph)***

The filled prescription data is analyzed to determine if differences between the filled prescription data and the unfilled prescription data are justified. ***(See method step 74, Fig. 4) (See specification, page 16, 2nd paragraph)*** If the discrepancy is unjustified, then a warning is generated. ***(See specification, page 16, line 22)*** The warning indicates that the prescription has been wrongly varied in some manner. The warning is sent to the physician who first wrote the prescription. ***(See method step 78, Fig. 4)*** The physician, upon receipt of the warning, can contact the patient or pharmacist to correct and mistake. ***(See specification, page 17, line 3-7)***

Claim 12

Claim 12 sets forth a method of verifying changes made by a pharmacist to medical prescriptions in order to reduce fraud and mistake in the filling of medical prescriptions ***(See Claim 12. preamble).*** The claimed methodology begins by entering unfilled prescription data into a secure database. ***(See method step 52, Fig. 3)*** After the prescription is filled, the filled prescription data that is generated is compared to the unfilled prescription data. ***(See method step 74, Fig. 4) (See specification, page 16, 2nd paragraph)*** This identifies any discretion exercised by the pharmacist. A warning is generated if the unfilled prescription data and the filled prescription data do not coincide. ***(See specification, page 16, line 22)***

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL [37 CFR §41.37(c)(6)]

The grounds of rejection to be reviewed on appeal are as follows:

1. **Whether the Examiner erred in rejecting Claims 1 – 6, 8-9 and 12-18 under 35 USC 103(a) as being unpatentable over US Pat App Pub No. 2004/0107117 to Denney in view of US Pat App Pub No. 2003/0074225 to Borsand.**

2. Whether the Examiner erred in rejecting Claims 10, 11, 19 and 20 under 35 USC 103(a) as being unpatentable over US Pat App Pub No. 2004/0107117 to Denney in view of US Pat App Pub No. 2003/0074225 to Borsand and in further view of US Pat App Pub No. 2001/0047281 to Keresman.

VII. ARGUMENTS. [37 CFR §41.37(c)(7)]

GROUND 1 - Whether the Examiner erred in rejecting Claims 1 – 6, 8-9 and 12-18 under 35 USC 103(a) as being unpatentable over US Pat App Pub No. 2004/0107117 to Denney in view of US Pat App Pub No. 2003/0074225 to Borsand

The rejected claims contain two independent claims, which are Claim 1 and Claim 12. Both Claim 1 and Claim 12 are believed to be distinguishable over both the Denny and Borsand references as is explained below.

Claim 1

Claim 1 sets forth a method of analyzing changes made by a pharmacist when filling a medical prescription.

It will be understood that when a pharmacist fills a prescription, the pharmacist often

changes the prescription to suit circumstances. For instance, if a prescription calls for 10 pills of 100 grams each and the pharmacy only has 50 gram pills, the pharmacist may fill the prescription with 20 pills of the 50 grams pills and instruct the patient to take two pills at a time. Similarly, many pharmaceuticals are made by more than one company. A pharmacist often uses his/her discretion in selecting the pharmaceutical to give to the patient.

Although the use of a pharmacist's discretion is commonplace, it can lead to mistakes, and to fraud. The present invention methodology is intended to detect when a mistake or fraud occurs. To achieve this method, a database is provided. In a physician's office, a physician examines a patient and writes a prescription for that patient. The prescription is initially unfilled. Unfilled prescription data that corresponds to the prescription is entered into the database. The unfilled prescription data contains information regarding a recommended pharmaceutical type and a recommended quantity recommended by the physician in the prescription.

The patient travels to a pharmacy to have the prescription filled. At the pharmacy, the unfilled prescription data is retrieved from the database. Using the retrieved data, the prescription is filled. The filled prescription contains a presented pharmaceutical type in a presented quantity. Due to the discretion of the pharmacist, the actual pharmaceutical presented and its quantity may not correspond with the unfilled prescription data. The discrepancy may be justified or unjustified and can be caused by mistake, fraud or simple pharmacist choice.

Data corresponding to how the prescription is actually filled is entered into the database by the pharmacist. The filled prescription data includes information regarding the actual presented pharmaceutical type and its quantity.

The filled prescription data is analyzed to determine if differences between the filled prescription data and the unfilled prescription data are justified. If the discrepancy is unjustified, then a warning is generated. The warning indicates that the prescription has been wrongly varied in some manner. The warning is sent to the physician who first wrote the prescription. The physician, upon receipt of the warning, can contact the patient or pharmacist to correct and mistake.

The Denny reference shows a database system for ensuring that a prescription is properly filled. Like the present invention, a physician enters a prescription into a database. Furthermore, like the present invention, a pharmacist recalls the prescription from the database. In this manner, the need for a handwritten prescription is eliminated.

However, the present invention method significantly differs from the Denny reference in how the data from the database is used. In the present invention, the pharmacist is required to enter any changes to the prescription that the pharmacist may have made using the pharmacist's discretion. The filled prescription data contains information regarding how the pharmacist changed the prescription. The data about the changed prescription is analyzed to see if the change is reasonable. If unreasonable because of mistake or fraud, a warning is sent back to the physician who wrote the prescription.

The Denny reference makes no disclosure concerning the method step of analyzing changes in the way a pharmacist alters a prescription to determine if the change is justifiable discretion or an unjustifiable mistake. The Denny reference makes no disclosure of entering any form of information regarding how a pharmacist may have changed the prescription. Likewise, the Denny reference makes no disclosure concerning the step of analyzing the pharmacists' change to see if it is merely justifiable discretion or an unjustifiable mistake.

The applicant specifically claims the method step of:

> ***"entering filled prescription data into said database should said presented pharmaceutical type or said presented quantity vary in any manner from said recommended pharmaceutical type or said recommended quantity stated in said prescription, wherein said filled prescription data includes information for said presented pharmaceutical type and said presented quantity actually present in said filled prescription;"***

In the final Official Action dated October 18, 2007, the Examiner states that the claimed method step of entering filled prescription data is disclosed in the Denny reference in paragraphs [0035] and [0041]. This is clearly not true.

The Applicant has reproduced paragraphs [0035] and [0041] of the Denny reference below. Paragraph [0035] is reproduced below

> [0035] Referring now to FIG. 3, one embodiment of the pharmacy system 16 is shown. The pharmacy system 16 includes an input device 70, an output device 72, a central processing unit (CPU) 74, a printer 76, and the communication channel 20. The users of the pharmacy system 16, such as pharmacists, pharmacists' assistants, and administrative personnel associated with the pharmacy, can input **information representative or indicative of a prescription to be filled** into the pharmacy system 16 via the input device 70 to retrieve the retrieval information discussed above, and, in some instances when authorization is obtained by a physician, to input the prescription information. The input device 70 may be any device capable of inputting information into the pharmacy system 16, such as a keyboard, mouse, scanner, voice-recognition, or other similar devices. The information input into the input device 70 is transmitted along line 78 to the central processing unit 74 for communication to the host system 12 via the communication channel 20. (Underline and bold added)

As can clearly be seen from the above, paragraph [0035] of the Denny reference merely states that a pharmacist can input *"information representative or indicative of a prescription to be filled'* into a computer system to "*retrieve*" information about that prescription. Paragraph [0035] makes absolutely no disclosure concerning entering information about how a prescription was actually altered and filled by a pharmacist into a database. The data to be entered into the database is for a prescription "*to be filled*" not one that has been filled.

Paragraph [0041] of the Denny reference is reproduced below.

> 0041] Once the pharmacy system 16 is connected to the host system 12, the host system 12 processes prescription information received from the pharmacy system 16 during a step 128 and a line 130. For example, after receiving a prescription, the patient can travel to one of the patient-selected pharmacies and present the printout of the prescription information to a pharmacist. The pharmacist enters the unique code identifying the prescription or other information identifying the patient into the pharmacy system 16 to affect retrieval of the prescription from the host system 12. During the step 128, the patient prescription information is received by the pharmacy system 16 from the host system 12, the prescription is filled by the pharmacist associated with the pharmacy system 16, and **a confirmation code indicative of a prescription being filled is input into the host system 12 by the pharmacy system 16. Thereafter, the pharmacy system 16 disconnects from the host system 12**, such as by terminating the Internet browsing software of the pharmacy system 16 as indicated in FIG. 4 by a step 132 and a line 134. (Underline and bold added)

In paragraph [0041] it merely states that the "confirmation code" corresponding to a prescription is entered into a database. "Confirmation code' has no known standard definition. Accordingly, we turn to the specification of the Denny reference for its definition. The term "confirmation

code' is first used and defined in the Denny reference in paragraph [0024], which states:

> The host system 12 is also capable of receiving, storing, and dispensing information representative of the fulfillment of the prescription identified by the prescription information and assigning **a confirmation code** to the prescription information so as to indicate whether or not the prescription has been filled.

In the Denny reference, it is clearly stated that the initial prescription is read from a database. The initial prescription comes with a "confirmation code". The confirmation code is entered to inform the database to confirm "***whether or not the prescription has been filed***". In other words, the confirmation code is merely a code number that is entered when a prescription is filled. The code number confirms to the database that the prescription was filled. It is clear that the Denny reference makes absolutely no disclosure of inputting data of how a prescription was filled, it merely receives a code that confirms the prescription was filled.

The Examiner cites the Denny reference in combination with the Borsand reference. **The Borsand reference** presents a system for tracking prescriptions to make the communications between a patient and a Pharmacy Benefit Manage (PBM) more efficient. However, like the Denny reference, the Borsand patent does not disclose a database where a pharmacist enters changes in a prescription caused by the use of the pharmacist's discretion. Furthermore, like Denny, the Borsand patent discloses nothing about analyzing the pharmacist's actions to determine if the change made by the pharmacist was either justified or not justified. Lastly, like Denny, the Borsand reference makes no disclosure concerning the creation of a warning if the changes made by a pharmacist were unjustified.

It should therefore be understood that as applied specifically to the wording of Claim 1, the combined Denny and Borsand reference s fail to disclose the method step of

> "***entering filled prescription data into said database, wherein said filled prescription data identifies said at least one pharmaceutical and volume actually provided by said pharmacist as said filled prescription;***

Likewise, the combination fails to disclose the claimed method step of:

> ***"comparing said filled prescription data to said unfilled prescription data to identify discretion exercised by said pharmacist; and"***

Lastly, the combination fails to disclose the claimed method step of:

> ***"generating a warning if said discretion exercised by said pharmacist is unjustified."***

In combination, it is clear that neither the Denny reference nor the Borsand reference disclose or suggest the method of Claim 1. Consequently, the combination fails to support a 35 USC 103 rejection. It is therefore requested that the 35 USC 103 rejection as applied to Claim 1 and its dependent claims be withdrawn.

Claim 12

Claim 12 sets forth a method of verifying changes made by a pharmacist to a prescription in order to reduce fraud and mistake.

In Claim 12, it is assumed that the pharmacist uses his/her discretion and alters a prescription when filling the prescription. More specifically Claim 12 contains the method step of

> ***"having a pharmacist at said pharmacy fill said unfilled prescription, wherein said pharmacist exercises discretion to alter said prescription so that the filled prescription varies from said unfilled prescription data;"***

The discretion exercised by the pharmacist is entered into a database and analyzed to see if the change was either justified or not justified. A warning is generated if the pharmacist's discretion turns out to be unjustified.

As has been previously explained, the Denny and Borsand references do not disclose or suggest a database where a pharmacist enters changes in a prescription caused by the use of the pharmacist's discretion. Furthermore, the Denny and Borsand references fail to disclose anything about analyzing the pharmacist's actions to determine if the change made by the pharmacist was either justified or not justified. Lastly, like Denny, the Borsand reference makes no disclosure

concerning the creation of a warning if the changes made by a pharmacist were unjustified.

In combination, it is clear that neither the Denny reference nor the Borsand reference disclose or suggest the method of Claim 12. Consequently, the combination fails to support a 35 USC 103 rejection. It is therefore requested that the 35 USC 103 rejection as applied to Claim 12 and its dependent claims be withdrawn.

GROUND -2.

Whether the Examiner erred in rejecting Claims 10, 11, 19 and 20 under 35 USC 103(a) as being unpatentable over US Pat App Pub No. 2004/0107117 to Denney in view of US Pat App Pub No. 2003/0074225 to Borsand and in further view of US Pat App Pub No. 2001/0047281 to Keresman.

Claims 10 and 11 depend from independent Claim 1. Claims 19 and 20 depend from independent Claim 12. The differences between the independent claims and the combined Denny and Borsand patents have been previously explained.

The Examiner cites the Keresman patent to show that biometric identification is used to identify health care professionals. However, the Keresman patent does not disclose or suggest any system where a pharmacist enters information regarding how the pharmacist altered a prescription. Accordingly, the Keresman patent does not disclose the deficiencies of the Denny patent or the Borsand patent as applied to the independent claims. Claims 10-11 and 19-20 are therefore believed to be patentable since they depend from, and further define, allowable base claims.

CONCLUSION

The Applicant's brief is believed to be in full compliance with 37 C.F.R. §41.37 et seq. The Examiner's 35 U.S.C. §103 rejections are not supported by the cited references. The Board is therefore requested to cause the Examiner to remove the rejections and allow the remaining

pending claims.

Respectfully Submitted,

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VIII. CLAIMS APPENDIX [37 CFR 41.47(c)(8).

The pending claims stand as follows:

1. A method of analyzing changes made to a medical prescription by, a pharmacist that fills said medical prescription, said method comprising the steps of:

providing a database;

entering unfilled prescription data into said database, wherein said unfilled prescription data corresponds to a prescription that has been prescribed by a physician to a particular patient, and wherein said unfilled prescription data contains information regarding a recommended pharmaceutical type and a recommended quantity prescribed in said prescription;

retrieving said unfilled prescription data from said database by a pharmacist selected by said particular patient to fill said prescription;

having the pharmacist fill said prescription utilizing said unfilled prescription data and present a filled prescription to said particular patient, wherein said filled prescription contains a presented pharmaceutical type in a presented quantity;

entering filled prescription data into said database should said presented pharmaceutical type or said presented quantity vary in any manner from said recommended pharmaceutical type or said recommended quantity stated in

said prescription, wherein said filled prescription data includes information for said presented pharmaceutical type and said presented quantity actually present in said filled prescription;

analyzing said filled prescription data to determine if differences between said filled prescription data and said unfilled prescription data are justifiable; and

generating a warning if differences between said filled prescription data and said unfilled prescription data are unjustifiable, wherein said warning is forwarded to said physician who initial wrote said prescription.

2. The method according to Claim 1, wherein said step of entering unfilled prescription data includes the substeps of:

having a physician access said database;

authenticating the identity of said physician; and

having said physician enter said unfilled prescription data into said database.

3. The method according to Claim 1, wherein said step of retrieving said unfilled prescription data from said database includes the substeps of:

having said medical service professional access said database;

authenticating the identity of said pharmacist; and

providing said pharmacist with said unfilled prescription data through said database.

4. The method according to Claim 1, further including the step of registering physicians authorized to access said database.

5. The method according to Claim 1, further including the step of registering pharmacists authorized to access said database.

6. The method according to Claim 1, wherein said step of entering filled prescription data further includes entering information regarding pharmaceutical brand and pharmaceutical cost.

7. (Cancelled)

8. The method according to Claim 1, wherein said step of generating a warning includes providing a warning to an insurance company that said pharmacist failed to properly fill said prescription.

9. The method according to Claim 1, wherein said database is

maintained at a central facility and said database is accessed by said physician and said pharmacist by a telecommunications link.

10. The method according to Claim 2, wherein said step of authenticating the identity of said physician includes verifying a biometric characteristic of said physician.

11. The method according to Claim 3, wherein said step of authenticating the identity of said pharmacist includes verifying a biometric characteristic of said medical service provider.

12. A method of verifying changes made by a pharmacist to medical prescriptions to reduce fraud and mistake in the filling of medical prescriptions, said method comprising the steps of:

entering unfilled prescription data into a secure database, wherein said unfilled prescription data corresponds to a patient's unfilled prescription for at least one pharmaceutical;

retrieving said unfilled prescription data from said database at a pharmacy;

having a pharmacist at said pharmacy fill said unfilled prescription, wherein said pharmacist exercises discretion to alter said prescription so that the filled prescription

varies from said unfilled prescription data;

entering filled prescription data into said database, wherein said filled prescription data identifies said at least one pharmaceutical and volume actually provided by said pharmacist as said filled prescription;

comparing said filled prescription data to said unfilled prescription data to identify discretion exercised by said pharmacist; and

generating a warning if said discretion exercised by said pharmacist is unjustified.

13. The method according to Claim 12, wherein said step of entering unfilled prescription data includes the substeps of:

having a physician access said database;

authenticating the identity of said physician; and

having said physician enter said unfilled prescription data into said database.

14. The method according to Claim 12, wherein said step of retrieving said unfilled prescription data from said database includes the substeps of:

having said pharmacist access said database;

authenticating the identity of said pharmacist; and

providing said pharmacist with said unfilled prescription data through said database.

15. The method according to Claim 12, further including the step of registering physicians authorized to access said database.

16. The method according to Claim 12, further including the step of registering pharmacists authorized to access said database.

17. The method according to Claim 12, wherein said step of generating a warning includes providing a warning to said physician.

18. The method according to Claim 12, wherein said step of generating a warning includes providing a warning to an insurance company.

19. The method according to Claim 13, wherein said step of authenticating the identity of said physician includes verifying a biometric characteristic of said physician.

20. The method according to Claim 14, wherein said step of authenticating the identity of said pharmacist includes verifying a biometric characteristic of said pharmacist.

IX. EVIDENCE APPENDIX [37 CFR 41.37(c)(1)(ix)].

There is no evidence submitted under 37 CFR 1.130, 1.131 or 1.132 or any other evidence relied upon by the applicant

X. RELATED DECISION APPENDIX [37 CFR 41.37(c)(1)(x)].

There are no decisions by a court or the Board relevant to this appeal.